K101234

510(k) Summary

AUG 25 2011

Submitter: Ventana Medical Systems, Inc.
Contact: Judy Howe
Date Prepared (original): 30-Apr-2010
Date Revised: 26-Jul-2011

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K101234

Device Name	VENTANA anti-Helicobacter pylori (SP48) Rabbit Monoclonal Primary Antibody
	Common name: IHC laboratory test for detection of Helicobacter pylori
	Classification: 21CFR866.3110, Immunology and Microbiology Devices
	Product Code: LYR
Device Description	IHC *in vitro* diagnostic antibody directed against *H. pylori* organisms and visualized though the application of either of two standard chromogenic secondary detection kits to locate and bind primary antibodies bound to tissue samples. Use of either detection system results in a dark brown colored precipitate at the site of specific antibody binding.
Intended Use	VENTANA anti-Helicobacter pylori (SP48) Rabbit Monoclonal Primary Antibody is designed to qualitatively detect the presence of Helicobacter pylori in formalin-fixed, paraffin-embedded gastric biopsy tissue via light microscopy. Immunohistochemical staining with this antibody product may aid in the diagnosis of Helicobacter pylori infection. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
Summary of the new devices	VENTANA anti-Helicobacter pylori (SP48) is substantially equivalent to a commercially available predicate device. Ventana has evaluated the performance of VENTANA anti-Helicobacter pylori (SP48) by comparing it with Ventana Giemsa Staining Kit and H. pylori diagnosis obtained from enrollment pathology reports for the detection of *H. pylori* infection in gastric biopsy tissue for patients. The Ventana Giemsa Staining Kit is a qualitative histologic stain to differentiate leukocytes in bone marrow and other hematopoietic tissue (lymph nodes) in formalin fixed, paraffin embedded tissue and can also be used to demonstrate some microorganisms, including *H. pylori.* Geimsa stains all enteric bacteria blue while VENTANA anti-*Helicobacter pylori* (SP48) detects the whole *H. pylori* organism *in situ.* The characteristic helical shape and localization of the organisms within the crypts of the mucosa assist the clinician in making an accurate diagnosis of infection.
Non-clinical performance data	Non-clinical performance testing has been conducted to demonstrate performance characteristics of VENTANA anti-Helicobacter pylori (SP48). Results of tissue-specificity and precision testing are noted in the product package insert.
Clinical performance data	A Method Comparison study was conducted to demonstrate the percent positive and negative agreement rates for the comparison of VENTANA anti-H. pylori (SP48) Rabbit Monoclonal Primary Antibody with Ventana Giemsa Staining Kit for determining the presence of H. pylori at three independent clinical sites. A total of 294 cases were considered evaluable by both assay methods and were therefore included in the analyses of agreement rates between VENTANA anti-H. pylori (SP48) and Ventana Giemsa Staining Kit. Pooled data from all sites demonstrated positive agreement in

	136/139 human gastric biopsy tissue samples and negative agreement in 153/155 human gastric biopsy tissue samples between VENTANA anti-H. pylori (SP48) and Ventana Giemsa Staining Kit. Pooled data from all sites demonstrated positive agreement in 138/151 human gastric biopsy tissue samples, and positive and negative agreement in 144/145 human gastric biopsy tissue samples between VENTANA anti-H. pylori (SP48) and the H. pylori diagnosis obtained from enrollment pathology reports. Thus equivalent performance between Ventana's investigational product, VENTANA anti-H. pylori (SP48), and the comparator, Ventana Giemsa Staining Kit, was demonstrated by percent positive and negative agreement rates for VENTANA anti-H. pylori (SP48) relative to Ventana Giemsa Stain at 97.8% and 98.7%, respectively. Background acceptability rates were evaluated because the presence of high background staining could potentially interfere with interpretation of the assay. Pooled data from all sites demonstrated a slide staining acceptability rate for slide background in 298/299 human gastric biopsy tissue samples stained with VENTANA anti-H. pylori (SP48). Morphology acceptability rates were evaluated because poor morphology of the tissue/organisms could potentially interfere with the interpretation of the assay. Pooled data from all sites demonstrated a slide staining acceptability rate for slide tissue morphology in 298/299 human gastric biopsy tissue samples stained with VENTANA anti-H. pylori (SP48).

COMPARISON OF VENTANA ANTI-HELICOBACTER PYLORI (SP48) RABBIT MONOCLONAL PRIMARY ANTIBODY TO PREDICATE DEVICE, PYLO-PLUS, K052708

PARAMETER	PREDICATE DEVICE	PROPOSED DEVICE
PROPRIETARY NAME	PYLO-PLUS, K052708	VENTANA ANTI-HELICOBACTER PYLORI (SP48) RABBIT MONOCLONAL PRIMARY ANTIBODY
FDA CLASSIFICATION	CLASS I, NON-EXEMPT	CLASS I, NON-EXEMPT
INTENDED USE	PYLO-PLUS IS INTENDED FOR QUALITATIVE DETECTION OF THE UREASE ENZYME IN GASTRIC MUCOSAL BIOPSY SPECIMENS AND FOR THE PRESUMPTIVE DETERMINATION OF *HELICOBACTER PYLORI* IN SYMPTOMATIC ADULT PATIENTS.	VENTANA MEDICAL SYSTEMS' VENTANA ANTI-HELICOBACTER PYLORI (SP48) RABBIT MONOCLONAL PRIMARY ANTIBODY IS DESIGNED TO QUALITATIVELY DETECT THE PRESENCE OF *HELICOBACTER PYLORI* IN FORMALIN FIXED, PARAFFIN EMBEDDED GASTRIC BIOPSY TISSUE VIA LIGHT MICROSCOPY. IMMUNOHISTOCHEMICAL STAINING WITH THIS ANTIBODY PRODUCT MAY AID IN THE DIAGNOSIS OF *HELICOBACTER PYLORI* INFECTION. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR *IN VITRO* DIAGNOSTIC (IVD) USE.
SAMPLE	GASTRIC MUCOSAL BIOPSY SPECIMENS	FORMALIN-FIXED, PARAFFIN-EMBEDDED GASTRIC BIOPSY TISSUE
ASSAY METHOD	SEROLOGICAL REAGENT	IHC WITH SECONDARY DETECTION
TARGET	UREASE ENZYME	WHOLE ORGANISM
ASSAY FORMAT	MANUAL	AUTOMATED
DETECTION SYSTEM	DIRECT	INDIRECT
VISUALIZATION	INTERPRETATION BY COLORIMETRIC CHANGE FROM YELLOW TO BRIGHT	INTERPRETATION BY LIGHT MICROSCOPY

COMPARISON OF VENTANA ANTI-HELICOBACTER PYLORI (SP48) RABBIT MONOCLONAL PRIMARY ANTIBODY TO PREDICATE DEVICE, PYLO-PLUS, K052708		
PARAMETER	**PREDICATE DEVICE**	**PROPOSED DEVICE**
PROPRIETARY NAME	**PYLO-PLUS, K052708**	**VENTANA ANTI-HELICOBACTER PYLORI (SP48) RABBIT MONOCLONAL PRIMARY ANTIBODY**
	MAGENTA	
INTENDED USE POPULATION	GASTRIC BIOPSY FROM PATIENTS SUSPECTED OF HAVING *H. PYLORI*	GASTRIC BIOPSY FROM PATIENTS SUSPECTED OF HAVING *H. PYLORI*
QUALITATIVE OR QUANTITATIVE	QUALITATIVE	QUALITATIVE
CONCLUSION	VENTANA ANTI-HELICOBACTER PYLORI (SP48) IS SUBSTANTIALLY EQUIVALENT TO PYLO-PLUS IN RELEVANT CHARACTERISTICS AND THE PERFORMANCE DIFFERENCES WILL NOT ADVERSELY AFFECT SAFETY AND EFFICACY.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

VENTENA Medical Systems, Inc.
c/o Ms. Judy Howe
Regulatory Affairs Specialist
1910 Innovation Park Drive
Tucson, AZ 85755

AUG 25 2011

Re: K101234

Trade/Device Name:	VENTANA anti-*Helicobacter pylori* (SP48) Rabbit Monoclonal Primary Antibody
Regulation Number:	21CFR §866.3110
Regulation Name:	*Campylobacter fetus* serological reagents
Regulatory Class:	Class I
Product Code:	OWF
Dated:	August 10, 2011
Received:	August 15, 2011

Dear Ms. Howe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section

510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K101234

Device Name: VENTANA anti-Helicobacter pylori (SP48) Rabbit Monoclonal Primary Antibody

Indications for Use:

VENTANA anti-Helicobacter pylori (SP48) Rabbit Monoclonal Primary Antibody (VENTANA anti-H. pylori (SP48)) is designed to qualitatively detect the presence of *Helicobacter pylori* in formalin-fixed, paraffin-embedded gastric biopsy tissue via light microscopy. Immunohistochemical staining with this antibody product may aid in the diagnosis of *Helicobacter pylori* infection. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls.

This antibody is intended for *in vitro* diagnostic (IVD) use.

Prescription Use _X_ AND/OR Over-the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Freddie M. Poole

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K 101234